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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,648	10/16/2001	Frank L. Graham	ADVEC10IA-C2	8065

29847 7590 06/03/2003

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EXAMINER
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KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
1636	11

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/981,648	GRAHAM ET AL.	
	<b>Examiner</b> Konstantina Katcheves	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 February 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 24-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 24-32 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

This Office action is in response to Paper No. 11, filed 24 February 2003. New claims 24-32 are pending in the present application. Claims 1-23 have been cancelled.

### ***Response to Amendment***

The rejections of claims 1-18, 22 and 23 are moot in view of the cancellation of these claims. Insofar as they are applicable, as Applicant's arguments in traverse of the rejections of record are addressed below.

### ***Rejections Necessitated by Applicant's Amendment***

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1636

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,379,943 for the reasons already of record in Office action mailed 11 September 2002. Applicant's acknowledgement of the rejection is noted and the examiner awaits the filing of a terminal disclaimer upon identification of allowable subject matter.

***Claim Rejections - 35 USC § 102***

Claims 24, 25, 28, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaleko (WO 97/25446).

As discussed in the prior Office action, Kaleko teaches a method for generating adenoviral vectors using recombinase-mediated transfer. See pages 5-9. The method uses a first polynucleotide including a heterologous DNA to be expressed, one adenoviral inverted terminal repeat (ITR), an adenoviral packaging signal and a recombinase target site. The second polynucleotide includes an adenoviral ITR. The second polynucleotide can also be a helper virus in which the adenoviral terminal protein is attached to the ITR. See page 12. As shown in, Figures 7, 10, 19, and 24, the helper virus can contain two ITRs. Although the DL327lox sequence in the figures is shown as linear, it is interpreted that the ITRs are in a head-to-head orientation. If the sequence had been depicted as a circle, it is presumably drawn in a linear fashion because the terminal proteins are attached. See also pages 26-27. Adenoviral proteins

for replication and packaging can be on the first polynucleotide, the second polynucleotide, a third polynucleotide provided by the cell, or any combination thereof. The packaging signal can be deleted from the adenoviral sequences. See pages 12-13. Applicant has argued that Kaleko fails to teach a circularized plasmid and a deletion in the packaging signal. Kaleko, on page 26, indicates that the plasmid comprising the head to head ITRs can be linearized. This implies that the plasmid can also be found in circularized form as claimed by Kaleko. Also on page 26, Kaleko specifically teaches that the packaging signal in the second polynucleotide has been deleted. The method of Kaleko teaches that a mutated gene can be found after recombination in the infectious adenovirus and thus can be useful because the mutated gene can be expressed throughout a tissue or organ. See page 29.

Claims 26, 27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the plasmids of these claims are required to practice the claimed inventions. Thus, these must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the plasmids. Although the Applicants describe the construction of the plasmids in the Figures, it is not clear that all of the nucleic acid sequences from which the plasmids were constructed are readily available to the public, and thus the plasmids of the claims may not be obtainable without

deposit. Applicant has argued generally that these plasmids can be reproduced by methods disclosed in the specification and supported by references incorporated by reference. Applicant has failed to specifically point out where this information can be found or whether these plasmids are commercially available. For example, figure 5E discloses plasmids pDC115, pDC116, pDC117 and pDC118 and their precursors. However, the figure and the accompanying description in the specification fail to teach the location or spacing of the various elements of the plasmids such that one of skill in the art may reliably reproduce the claimed plasmids.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
May 28, 2003

  
REMY YUCEL, PH.D  
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